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901 NORTH GLEBE ROAD, 11TH FLOOR			WHALEY, PABLO S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,581

Applicant(s)

PIOT ET AL.

Examiner

PABLO WHALEY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/25/2007.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-22 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 25 July 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/22)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date 4/4/2008

DETAILED ACTION

Status of Claims

Claims 1-22 are currently pending and under consideration.

Drawings

Drawings filed 07/25/2007 have been accepted.

Information Disclosure Statement

The information disclosure statement filed 04/04/2006 has been considered in full.

Specification

In the instant case, the specification is objected to as it contains non-standard section headings. See 37 CFR 1.77(b). This objection may be overcome by amending section headings to comply with 37 CFR 1.77(b). For example, pages 4 and 7 of the specification recite "OBJECTS AND SUMMARY OF INVENTION" and "MORE DETAILED DESCRIPTION."

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

According to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that

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weigh against the eligibility of a process under 35 U.S.C. 101 include: (i) No recitation of a machine or transformation (either expressed or inherent); (ii) Insufficient recitation of a machine or transformation (e.g. a general recitation of a machine that it covers any machine capable of performing the claimed method steps, or a recitation of the machine that is tangentially related to the performance of the steps or merely involves insignificant activity (e.g. data gathering); (iii) The claim is not directed to an application of a law of nature; and (iv) The claim is merely a statement of a general concept (e.g. abstract mathematical concepts or algorithms). It is noted that where the machine or transformation test (i.e. M-or-T test) is not met, analysis is extended to determine whether the claims read on an abstract idea. The prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (See *In re Comiskey*, Fed. Cir., No. 2006-1286, 9/20/07; *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972).

The claims are drawn to a method implemented by a computer. The claims result in deducing the initial population size in a sample of interest.

In the instant case, the claimed process is not tied to a particular machine. The preamble of claim 1 recites a method implemented by computer means to quantify an initial population of nucleic acids in a sample of interest subjected to a succession of applications of a population amplification reaction, during which experimental measurements are taken representative of a current size of the population of at least the sample of interest. However, the recitation the

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method being “implemented by computer” weights against eligibility under 35 U.S.C. 101, as discussed above, since the computer is generically recited such that it covers any machine capable of performing the claimed method steps. Thus, the recitation in the preamble that the methods are “computer implemented” does not “give life, meaning, and vitality to the claim” (see MPEP 2111.02). When analyzing the body of the claim, which requires steps for providing a model, using the model to express a relationship between data, determining a changeover index by comparison with data, and deducing the size of a population, these steps are totally directed to data manipulation, which is an abstract mathematical construct, not a practical application of a well-defined algorithm.

Furthermore, the claimed method does not transform (either explicitly or inherently) any particular physical article; e.g. by requiring that a particular physical assay is performed. Limitations direct to a population of nucleic acids in a sample of interest subjected to a succession of applications of a population amplification reaction, during which experimental measurements are taken representative of a current size of the population of at least the sample of interest, are noted. However, these limitations do not necessarily require physical measurement as it could be simply that a user takes the measurement data already physically measured, and are merely an intended use of the claimed method in the preamble. Thus, the claimed method is wholly directed to an abstract idea, and therefore is directed to non-statutory subject matter under 35 U.S.C. 101.

Claim 22 is rejected under 35 U.S.C. 101 because this claim is drawn to non-statutory subject matter. In the instant case, claim 22 is directed to a computer program product for storing instructions in a memory of a processor or on a removable memory medium. A review of the

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specification discloses both signals and physical memory; see page 30, Therefore the claim covers both transitory and non-transitory embodiments. The USPTO recognizes that applicants may have claims directed to computer readable media that cover signals per se, which the USPTO must reject under 35 U.S.C. § 101 as covering both non-statutory subject matter and statutory subject matter. In an effort to assist the patent community in overcoming a rejection or potential rejection under 35 U.S.C. § 101 in this situation, the USPTO suggests the following approach. A claim drawn to such a computer readable medium that covers both transitory and non-transitory embodiments may be amended to narrow the claim to cover only statutory embodiments to avoid a rejection under 35 U.S.C. § 101 by adding the limitation "non-transitory" to the claim. Cf. *Animals - Patentability*, 1077 Off. Gaz. Pat. Office 24 (April 21, 1987) (suggesting that applicants add the limitation "non-human" to a claim covering a multi-cellular organism to avoid a rejection under 35 U.S.C. § 101). Such an amendment would typically not raise the issue of new matter, even when the specification is silent because the broadest reasonable interpretation relies on the ordinary and customary meaning that includes signals per se. The limited situations in which such an amendment could raise issues of new matter occur, for example, when the specification does not support a non-transitory embodiment because a signal per se is the only viable embodiment such that the amended claim is impermissibly broadened beyond the supporting disclosure. See, e.g., *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998). The applicants are cautioned against introduction of new matter in an amendment.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claim 1 are also rejected due to said dependency.

Regarding claim 1: The preamble of claim 1 recites a method implemented by computer means to quantify an initial population of nucleic acids in a sample of interest subjected to a succession of applications of a population amplification reaction, during which experimental measurements are taken representative of a current size of the population of at least the sample of interest. In this case, these limitations are interpreted as intended use. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone [See MPEP 2111.02]. If applicant intends otherwise; e.g. if applicant intends for the claims to recite

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active method steps such as "performing amplification reactions" and "obtaining experimental measurements", the claims should be amended to recite these steps in the body of the claim.

Regarding claim 1, Step b): The claim recites the limitation "the changeover index." There is lack of antecedent basis for this limitation. The claim does previously recite an amplification index, however.

Regarding claim 1, Step c): The claim recites "determining at least the changeover index by comparison with the experimental measurements." It is unclear as to what is compared with the experimental measurements to determine at least the changeover index.

Regarding claim 1, step d): The claim requires "deducing therefrom the initial population size in the sample of interest." It is not clear what is meant by "therefrom". Furthermore, it is unclear what the initial population is deduced from; e.g. from the previous step of "determining" or parts thereof, or from the "comparison" or "experimental measurements." Clarification is requested.

Regarding claim 2: The claim recites "said succession of amplifications" ; see line 4. There is lack of sufficient antecedent basis for this limitation. There is no prior reference to a succession of amplifications in the claim or claim 1. However, claim 1 recites "a succession of applications" in the preamble. Additionally, the claim recites determiningthe changeover index by comparison with said experimental measurements; see lines 6-8. It is unclear as to WHAT is compared with the experimental measurements to determine at least the changeover index.

Regarding claims 6, 12, and 15: The claims recite "the index." In each case, it is unclear which index the claim is referring to; e.g. changeover index, amplification index, or otherwise.

Regarding claim 9: The claim recites "deriving a proportionality relationship therebetween." The term "therebetween" renders the claim indefinite. It is unclear as to what elements of the claim the derived proportionality relationship is between.

Regarding claim 15: The claim recites the limitation "said non-constant stage of the yield"; see lines 1-2 and "estimating a coarse value" see line 4. There is lack of antecedent basis for this limitation, as there is no prior reference to a non-constant stage of the yield in this claim or any of the parent claims 1 and 14. Additionally, it is unclear what is meant by a "coarse value"; see line 4. The specification does not provide any guidance. This term is interpreted as a threshold value for purposes of applying prior art. Additionally, the claim recites "at least when seeking the index in said changeover region"; See lines 6-8. This is confusing for two reasons. First, it is unclear what limitation of the claimed method is intended by the phrase "at least when seeking the index." This is interpreted as optional language for purposes of applying prior art. Second, it is unclear which index the claim is referring to; e.g. changeover index, amplification index, or otherwise. Clarification is requested.

Regarding claim 16: The claim recites the limitation "said non-constant stage of the yield"; see lines 1-2. There is lack of antecedent basis for this limitation, as there is no prior reference to a non-constant stage of the yield in this claim or any of the parent claims 1 and 14.

Regarding claim 17: The claim recites the limitation "the estimated value of said amplification index." There is lack of antecedent basis for "the estimated value". Additionally, the claim also recites "possibly to obtain a fractional value." It is unclear what limitation of the claimed method is intended by this phrase. This phrase is interpreted as an intended use of the estimated value of said amplification index for purposes of applying prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutledge et al. (Nucleic Acids Research, 2003, Vol. 31, No. 16 e93, p.1-6).

In view of the indefiniteness of the claims as set forth above, prior art is being applied the following interpretation of the claims.

The claims are drawn to a method to quantify an initial population of nucleic acids in a sample of interest subjected to a population amplification reaction of a succession of repeated amplification cycles, the method comprising:

- after experimental measurements are taken/obtained, representative of a current size of the population of the sample of interest;

- providing a model of the yield of the amplification reaction, this model corresponding to the variation of the yield as a function of the number of amplification cycles and represented by a curve having:

 - a first constant portion corresponding to a first part of the succession of repeated amplification cycles;

 - a second non-constant portion corresponding to a second part of the succession of repeated amplification cycles;

 - a changeover region uniting the first and second portions of the curve, said region having a changeover index equal to a corresponding number of amplification cycles;

- determining a relationship between the changeover index and a parameter representative of the initial population size in the sample of interest;

- determining an experimental variation of the yield and a changeover index value from the experimental measurements taken during the repeated amplification cycles, and

- determining the initial population size in the sample of interest from the changeover index value by means of the relationship between the changeover index and the said parameter representative of the initial population size.

Rutledge teaches a method and system for quantitative PCR involving mathematics of quantitative kinetic PCR and the application of standard curves. The method comprises taking

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measurement data of the yield of the amplification and providing a model of the yield of the amplification in function of the number of amplification cycle. See at least Fig. 1. The model is represented by a plurality of curves where each comprises a constant portion, a non-constant portion, and a changeover portion uniting the constant and non-constant portions. See Fig. 1A, where the flat region is the constant portion, the exponential region is the non-constant portion and the region in between is the changeover portion having a changeover index equal to a corresponding number of amplification cycles on the X-axis. Rutledge shows the use of the model in Fig. 1A for generating a standard curve to determine the slope and intercept points, which correspond to amplification efficiency and the number of amplicon molecules (i.e. initial population size) in the sample of interest; see Fig. 1B. and Legend. This process allows for deducing the initial concentration; i.e. population size, of the sample by comparing experimental measurement with the standard curve. Rutledge also provides a mathematical function (i.e. curve) for deducing the population size (N_c) at any point in the amplification process; see page 6, Col. 1, RESULTS.

It is noted that the instant specification also discusses Rutledge and states on pages 2-3 :

The document ... by R. G. Rutledge and C. cote ... discloses a method of estimating the unknown initial quantity of nucleic acids in a sample of interest by means of PCR. That method consists in using a plurality of samples having known initial quantities of nucleic acids, referred to as "standards", in order to determine by interpolation the initial quantity of nucleic acids present in the sample of interest.

Regarding limitations directed to parameterized variations representative of current population size, Rutledge teaches that intercept and slope vary with samples caused by inter-run variation in

instrumentations and/or amplification; see page 3 and Table 1, and use standard deviations of the Ct index parameter to estimate variation in population using a specific equation. These variations are interpreted as the parameterized variations of the instant claims. The slope and intercepts are determined substantially together; See page 4. Rutledge provides equations for determining amplification efficiency represented using the parameter “E”; see page 2, which is interpreted as yield.

Rutledge does not explicitly teach a step for determining the “changeover index” by comparison with experimental measurements, as in claim 1. However, this limitation would have been obvious to one of ordinary skill in the art at the time of the instant invention since Rutledge provides amplification reaction graphs, wherein the fluorescence threshold is interpreted as the point which defines the change from constant stage to non-constant stage; see Figure 1. Linear regression is used to determine the slope and intercept values at each of the threshold points; see Figure 1B and Legend. Therefore the slope values disclosed by Rutledge are reasonably interpreted as “crossover index” values, since they represent changes between the constant and non-constant stage of the amplification graphs and are based on experimental measurements.

Rutledge does not explicitly teach limitations directed to an installation and computer program product (i.e. program) for performing the method of claim 1, as set forth above.

In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure*, U.S. Trademark and Patent Office, section 2144.04, III).

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have performed any step of the previously stated methods of Rutledge according to *In re Venner*, since Rutledge describes the use of commercially available devices (i.e. an installation setup) for performing their method; see page 1, Col. 2, which includes a sample support for supporting at least a sample of interest, a first apparatus for applying a succession of amplification reactions, at least to a population of interest in the sample of interest; a second apparatus for taking measurements representative of a current size of the population of interest; software (Opticon 2) for determining experimental values; and exports data to MS Excel workbook for analysis. Therefore, the claimed invention, i.e. the computer program product comprising instructions to execute a process would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Rutledge et al.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rutledge et al. (Nucleic Acids Research, 2003, Vol. 31, No. 16 e93, p.1-6), in view of Gibson et al. (Genome Res., 1996, 6: 995-1001).

Rutledge makes obvious a method, installation, and computer program product as set forth above.

Rutledge does not teach subtracting background noise and introducing a compensation to take account of a non-zero measurements representative of the initial population size, as in claim 8.

Gibson teaches a method for using quantitative real time PCR. In particular, the method includes a step for subtracting background noise from measurements; and introducing the use of internal controls for normalizing fluorescence emissions; see page 996, RESULTS.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have subtracted background noise, as taught by Gibson, in the method made obvious by Rutledge, since Rutledge also teaches fluorescent monitoring of DNA amplification with predictable results. The motivation would have been to use internal controls in the amplification process, as suggested by Gibson, page 996, RESULTS. It would further have been obvious to someone of ordinary skill in the art at the time of the instant invention to have introduced a compensation to account for non-zero measurements, in the method made obvious by Rutledge, since Rutledge suggests the PCR process is error prone; see page 1, Col. 2, and since Gibson teaches introducing internal controls into the process, as set forth above, which meet the claim language for introducing a compensation. The motivation would have been to normalize fluorescence emission, as suggested by Gibson; see page 996, RESULTS.

Provisional Obviousness-Type Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA

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1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

The conclusion of obviousness-type double patenting is made in light of these factual determinations. Any obviousness-type double patenting rejection should make clear: (A) The differences between the inventions defined by the conflicting claims; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the patent.

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-12, 14-20, and 23-27 of copending Application No. 10/998175.

In the instant case, the differences between the inventions defined by the conflicting claims are as follows: the instant claims and the copending claims both recite a relationship between the changeover index and a parameter representative of the population size. However, the copending claims present a formula that falls within the scope of the mathematical relationship between the changeover index and a parameter representative of the population size, which is presented in the instant claims. In other words, the copending claims present a formula that is a species of the genus of the relationship set forth in the instant claims. Therefore a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined the copending claims, since the instant claims are generic to a species of mathematical relationship set forth in the copending application. See MPEP 804. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley
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/PW/

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